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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/877,748 | 06/11/2001 | John W. Sutherland | CDS-232 | 5214 |

27777 7590 06/10/2003

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EXAMINER

WILDER, CYNTHIA B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1637

10

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/877,748

Applicant(s)
SUTHERLAND J.

Examiner
Cynthia B Wilder

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 11, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12, drawn to a method of detecting a mutant nucleic acid, classified in class 435, subclass 6.
 - II. Claims 13-17, drawn to a method of quantitating nucleic acids, classified in class 435, subclass 91.1.
 - III. Claims 18-20, drawn to a composition and kit, classified in class 536, subclass 23.1.

Sequence Election Requirement Applicable to Group III

In addition, Group III detailed above reads on patentably distinct SEQ ID Number sets. Each of the sequences are patentably distinct because the sequences are structurally unrelated sequences and a further restriction is applied to that Group. Applicant must further elect **one** (single) SEQ ID Number selected from the group consisting of SEQ ID NOS: 2-4, 6-13, 15-17, 19, 21-25 and 27-32 if the Group III is elected.

Applicant is advised that examination will be restricted to only the elected *single* SEQ ID NOS: and should not be construed as a species election. Non-elected sequences in multiple sequence claims will be withdrawn from prosecution.

2. The inventions are distinct, each from the other because of the following reasons:

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Inventions I and II are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different starting material, different modes of operation leading to different effects. For example, the method of invention I drawn to a method of detecting a mutant nucleic acid utilizes mutant primers in a PCR reaction to identify the presence of amplicons in a target sample whereas the method of invention II drawn to a method of quantitating nucleic acids utilizes real-time amplification to quantitate the a nucleic acid having a deletion sequence. The different inventions are patentably distinct requiring different fields of search.

3. Inventions III and I, II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product comprising the composition and kit can be used in a materially different process such as in methods of nucleic acid hybridization for the objective of detecting a polymorphism in the sample or for genetic mapping studies. Optionally, the composition and kit can be used in nucleic acid cloning studies or nucleic acid purification studies.

4. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

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5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). A fully responsive reply will comprise the election of both a particular single sequence to be examined along with the corresponding claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Group's receptionist at (703) 308-0196.

cbw
June 6, 2003


Cynthia B. Wilder, Ph.D.
Patent Examiner
Art Unit 1637